Congress of the United States

Washington, DC 20515

January 26, 2023

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Commissioner Califf:

We write to express our profound opposition to the Food and Drug Administration (FDA) action on January 3, 2023, to reiterate its decision to eliminate the in-person dispensing requirement for the chemical abortion drug mifepristone (in combination with misoprostol), and to allow retail and mail-order pharmacies to become certified to dispense abortion drugs. The FDA's action promotes dangerous do-it-yourself abortions by mail and telemedicine without ever seeing a doctor in person, and turns brick-and-mortar pharmacies and post offices into abortion centers. Through this abuse of discretion, the FDA has put the profits and political agenda of the abortion industry over the science and clear evidence that abortion drugs present grave dangers to pregnant mothers and their unborn babies. The action also violates Federal criminal law for reasons made clear in a recent Federal lawsuit by the Alliance for Hippocratic Medicine.[1] We call on the FDA to remove mifepristone from the market, or, at minimum, promptly restore and further strengthen the initial basic health and safety requirements for abortion drugs, and cease permitting the mailing and shipping of abortion drugs in violation of Federal criminal law.

A. Threats to the Health and Safety of Pregnant Mothers

The FDA's removal of the commonsense in-person dispensing requirements for abortion drugs abandons pregnant mothers to suffer alone, without proper medical evaluation or oversight, potentially life-threatening complications, which can include severe bleeding, infection, potential surgical intervention, and even death.[2] As you know, under the previous Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program, to mitigate these dangers, abortion drugs had to be ordered, prescribed, and dispensed in-person by a qualified healthcare provider in a clinic, medical office, or hospital. Under the FDA's new de-facto no-test abortion drug regime, a pregnant mother can obtain life-ending abortion drugs at a retail pharmacy or through the mail with as little as a phone call with the prescribing abortionist.[3] This denies pregnant women the chance to be first clinically screened in-person by a doctor to rule out contraindications like an ectopic pregnancy (which occurs in about 1 in 50 pregnancies, and is life-threatening), to

[1] Alliance for Hippocratic Medicine, et alia v. U.S. Food and Drug Administration, filed in the U.S. District Court for the Norther District of Texas, Amarillo Division https://adflegal.org/sites/default/files/2022-11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Complaint.pdf.

[2] Niinimäki, Maarit et al. "Immediate complications after medical compared with surgical termination of pregnancy." *Obstetrics and gynecology* vol. 114,4 (2009): 795-804. doi:10.1097/AOG.0b013e3181b5ccf9

[3] This violates Federal criminal laws prohibiting the mailing and shipping of abortion drugs, as explained further on.

accurately determine the age of the baby to prevent life-threatening complications,[4] and to provide Rh screening to protect their future fertility.[5]

Dispensing abortion drugs through mail-order and retail pharmacies removes safeguards to ensure the drugs are taken immediately and by the woman for whom the drug is specifically prescribed. It consequently makes it easier for these drugs to fall into the hands of human traffickers or abusers, who may administer the drugs to pregnant mothers without their knowledge or consent.[6] In addition, despite its directive that mail-order abortion drugs be delivered within four days of the prescription, without ultrasound confirmation of gestational age and with possible shipping delays, the REMS modification will likely increase the incidence of the dangerous use of abortion drugs later in pregnancy, beyond the 70-day gestational limit under the REMS. This further increases the risks of complications.[7]

Under the FDA's action, abortionists are able to profit from selling abortion drugs to women and girls, while reducing their overhead costs and offloading care for ensuing complications onto local medical systems and emergency rooms.[8] The FDA admits that the distribution of abortion drugs by mail after a telemedicine visit has been demonstrated to cause increased adverse events through "higher ED [emergency department]/urgent care visits."[9] More generally, the FDA's further weakening of the REMS will exacerbate the alarmingly high rates of dangerous complications under the FDA's previous abortion drug regime. One study, which examined Medicaid claims data from the 17 states where taxpayers fund abortion on demand, found that the rate of abortion-related emergency room visits following a chemical abortion increased by more than 500 percent from 2002 through 2015. This study also found that chemical abortions are more than 50 percent more likely than surgical abortions to result in an emergency room visit within 30 days.[10] Another recently published study found that, compared to surgical abortion,

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[4] The American College of Obstetricians and Gynecologists' clinical guidance notes that a significant percentage of women have their due date changed by 5 days or more following a first trimester ultrasound: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.

[5] Skop, Ingrid, "The Evolution of "Self-Managed" Abortion: Does the Safety of Women Seeking Abortion Even Matter Anymore?", March 1, 2022, Charlotte Lozier Institute, https://lozierinstitute.org/the-evolution-of-self-managed-abortion.

[6] Ibid.

[7] The risk of needing a surgical abortion following a chemical abortion at 10 weeks is about 1 in 12 (or 8%). Just 3 weeks later, at 13 weeks gestation, this increases dramatically to 1 in 3 women. *See* Mentula MJ, Niinimäki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Hum Reprod. 2011 Apr;26(4):927-32. doi: 10.1093/humrep/der016. Epub 2011 Feb 11. PMID: 21317416

[8] In order to provide appropriate treatment in such cases, it is critical that physicians treating complications arising from abortion drugs are aware of their use. We, therefore, are concerned that the FDA's REMS modification has removed a certification from the patient agreement which stated, "I will take [the Medication Guide for Mifepristone] with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone."

[9] FDA Summary Review, Mifepristone REMS Modification Rationale Review, pg. 39 https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf#page=79 18 U.S.C. 1961(1)

[10] Studnicki, James et al. "A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015." *Health services research and managerial epidemiology* vol. 8 23333928211053965. 9 Nov. 2021, doi:10.1177/23333928211053965

chemical abortion was associated with significantly higher reports of serious adverse events, emergency room visits, and subsequent surgical abortion.[11]

B. The FDA's actions violate its legal obligations to protect patient safety.

As the Alliance for Hippocratic Medicine has argued in a Federal lawsuit filed in November 2022, the FDA has failed to abide by its legal obligations to protect the health, safety, and welfare of women and girls in approving and subsequently weakening protections surrounding chemical abortion drugs. In 2000, the Clinton administration FDA first approved mifepristone, referred to then as RU-486, to be used for abortions in conjunction with misoprostol, under a highly politicized, expedited approval process that exceeded the FDA's authority. In order to use the expedited approval process known as Subpart H, the FDA wrongly and, therefore, illegally treated pregnancy as an "illness" and asserted that the drugs provide "meaningful therapeutic benefit" over existing treatments.[12] The FDA also failed to comply with its obligations under Federal law to demonstrate the safety of the drugs under the labeled conditions[13] and to assess the potential impacts on adolescent girls.[14] The FDA's further weakening of the health and safety requirements in the Mifepristone REMS Program in 2016, in 2021, and now reiterated again in 2023, suffer from some of the same legal defects as the 2000 approval.

The FDA's justification for eliminating the in-person dispensing requirement fails to include any studies or evidence that meet the statutory requirement to demonstrate the safety and effectiveness of the drug under the new labeled conditions. The FDA's conclusion heavily relies on the small number of adverse events collected from the drug manufacturers and the FDA's Adverse Event Reporting System during periods when the in-person dispensing requirement was not being enforced since 2020. However, the FDA ignores the fact that this is not evidence of safety, but merely the logical consequence of the FDA's action in 2016 to remove the requirement for providers who prescribe abortion drugs to report non-fatal adverse events.

The FDA's conclusion cites cherry-picked studies from the abortion industry and a handful of pro-abortion academics, and improperly disregards evidence of the harms and risks. Critically, the main studies cited by the FDA suffer from deficiencies, and fail to replicate the new labeled conditions.[15] Unlike the FDA's approved regime, several of these studies included an ultrasound, exam, or other testing before the dispensing of the abortion drugs, making them unreliable in ascertaining the safety of dispensing abortion drugs without those requirements. While the FDA acknowledges "the studies assessing mifepristone dispensing by mail suggest more frequent encounters with healthcare providers," that is, more frequent emergency room

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[11] Liu, Ning, and Joel G Ray. "Short-Term Adverse Outcomes After Mifepristone-Misoprostol Versus Procedural Induced Abortion : A Population-Based Propensity-Weighted Study." Annals of internal medicine, 10.7326/M22-2568. 3 Jan. 2023, doi:10.7326/M22-2568

[12] *See* Subpart H, 21 C.F.R. § 314.500

[13] *See* 21 U.S.C. 355(d)

[14] *See* 21 U.S.C. 355c

[15] FDA Summary Review, Mifepristone REMS Modification Rationale Review, pg. 35 https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf#page=75 It is highly inappropriate that the FDA cites in support of its actions a study from Women on the Waves, a sister organization to Aid Access, an overseas abortion pill mill. The FDA in 2019 sent a warning letter to Aid Access for unlawfully importing unapproved abortion drugs into the United States.

visits to treat complications, it nevertheless concludes such dispensing methods are safe without a reasonable or scientific basis.[16]

In a telling admission, the FDA states: "Despite the limitations of the studies we reviewed, we conclude that overall, the outcomes of these studies are *not inconsistent with our conclusion*" (emphasis added) regarding the safety of removing the in-person dispensing requirement.[17] Once again, the FDA gets it backward. FDA has the burden to establish safety before weakening safety standards. Rather than letting science and evidence drive its decision making, the FDA has operated at every turn to advance a predetermined conclusion to expand abortion drugs, despite evidence of harm.

C. The FDA's sanctioning of the mailing and shipping of abortion drugs violates longstanding Federal criminal law

The FDA's original approval for mifepristone in 2000 and subsequent weakening of associated patient safeguards in 2016, in 2021, and now reiterated in 2023, failed to acknowledge or comply with longstanding Federal criminal laws prohibiting the mailing and shipment by common carrier of abortion drugs. In fact, the newly modified REMS explicitly sanctions the shipping of abortion drugs: it does so first from the drug manufacturer to pharmacies, and secondly by requiring certified pharmacies to be able ship the drugs directly to patients. In so doing, the FDA is, astonishingly, conditioning certification for pharmacies on their willingness to violate Federal criminal law.

Section 1461 of title 18 of the U.S. Code imposes felony criminal liability on the mailing of "[e]very article or thing designed, adapted, or intended for producing abortion" and "[e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." Section 1462 of title 18 of the U.S. Code, applies similar criminal penalties for importing, or using a common carrier (like FedEx) "for carriage in interstate or foreign commerce . . . any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." Violations of these laws are also predicate offenses under the Racketeer Influenced and Corrupt Organizations Act (RICO), which provides for extended criminal penalties and a civil cause of action.[18]

Even if the FDA's removal of the in-person dispensing requirement were otherwise lawful, it would not nullify or supersede the additional obligation to comply with these Federal laws (and State laws) prohibiting the mailing or shipping of abortion drugs.[19] The recent U.S. Department of Justice Office of Legal Counsel (OLC) opinion to the U.S. Postal Service that these Federal laws do "not prohibit the mailing of certain drugs that can be used to perform abortions where the sender lacks the intent that the recipient of the drugs will use them unlawfully," wrongfully

[16] Ibid.
[17] Ibid.
[18] 18 U.S.C. 1961(1)
[19] In the preamble to a final rule limiting the mailing of e-cigarettes promulgated last year, USPS observed, as equally applies here, that "FDA authorization . . . for introduction or delivery into interstate commerce does not absolve an actor from other Federal requirements . . . : Rather, all overlapping requirements must be complied with in order to offer the product in interstate commerce." https://www.federalregister.gov/documents/2021/10/21/2021-22787/treatment-of-e-cigarettes-in-the-mail

disregards the plain text and clear meaning of the law.[20] The OLC opinion has no legally binding force, and does not prevent a future administration from enforcing the plain text and clear meaning of these laws, including within the five-year statute of limitations.[21]

Indeed, these Federal criminal laws continue to be "the supreme law of the land," because Congress has never repealed them, and, in fact, has amended and strengthened them as recently as 1994 and 1996. Moreover, the provisions of law prohibiting the mailing and interstate and international carriage of abortion drugs have never been enjoined by any Federal court. In fact, one Federal court has recently acknowledged that these laws are currently in effect.[22]

D. The FDA's action threatens the conscience rights of pharmacists

In addition to harming patient safety, the FDA's action also threatens the conscience rights of pharmacists who do not want to participate in abortion, but who are employed by certified pharmacies. The modified REMS provides no protections for pharmacists who object to abortion, and fails to acknowledge longstanding Federal conscience laws, including the Weldon Amendment, the Church Amendments, and the Coats-Snowe Amendment, which protect health care professionals who do not participate in abortions. Instead, the Biden administration has already issued a legally-flawed directive that threatens pharmacists who have conscience-based objections to dispensing abortion drugs.[23]

E. Conclusion

The FDA's action of January 3, 2023, to reiterate its decision to eliminate the in-person dispensing requirement from the Mifepristone REMS program, permitting retail and mail-order pharmacies to dispense abortion drugs, is dangerous, reckless, and illegal. Through its decision to permit no-test, mail-order abortions after a telemedicine visit, the FDA has abandoned its dual obligations to protect the public and vulnerable populations from harm and to comply with Federal law, including Federal requirements to protect patient safety and longstanding Federal criminal laws which expressly prohibit the mailing and shipping of abortion drugs. We therefore insist that the FDA pull the deadly drug mifepristone from the market, or, at minimum, promptly restore and further strengthen the initial basic health and safety requirements for abortion drugs, and comply with Federal criminal law.

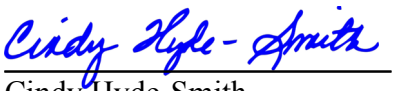
Sincerely,

[20] https://www.justice.gov/olc/opinion/file/1560596/download

[21] See *Dist. of Columbia v. John R. Thompson Co.,* 346 U.S. 100, 113–14 (1953) ("The failure of the executive branch to enforce a law does not result in its modification or repeal.").

[22] *See* Texas v. Becerra, No. 5:22-CV-185-H (N.D. Tex.), footnote 21.

[23] HHS Office for Civil Rights, Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services, https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf



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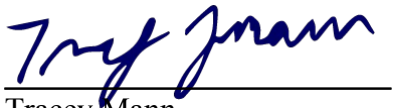

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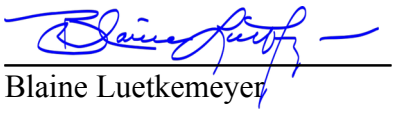

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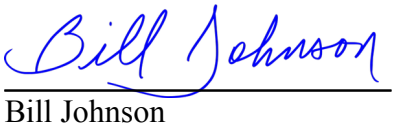

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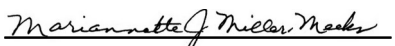

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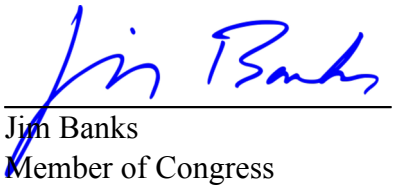

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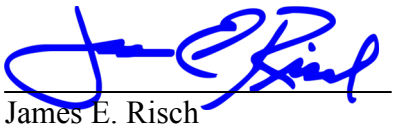

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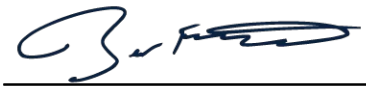

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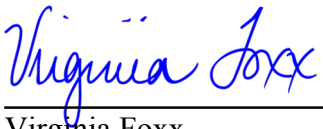

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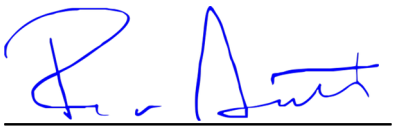

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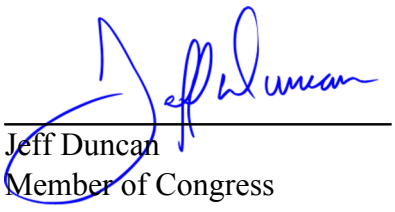

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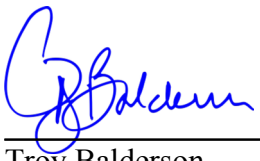

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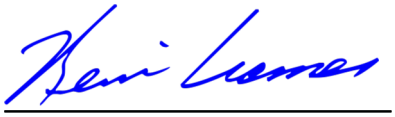

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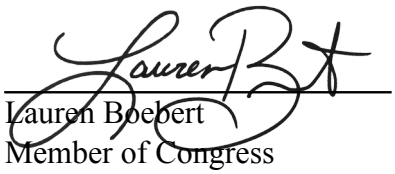

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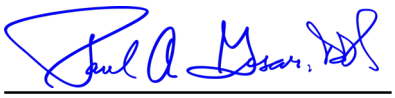

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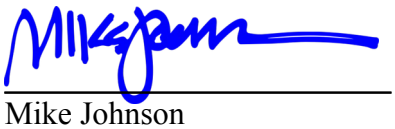

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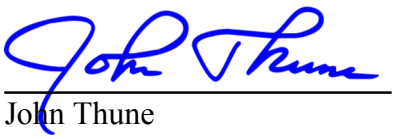

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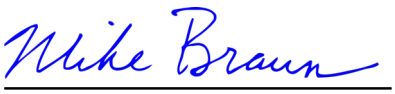

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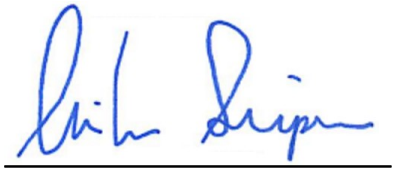

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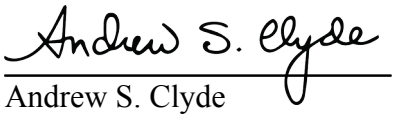

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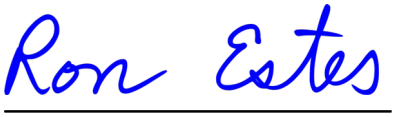

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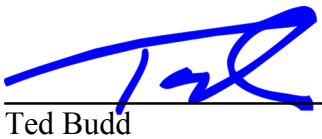

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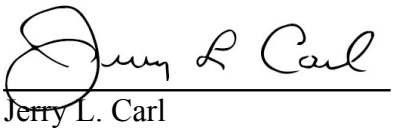

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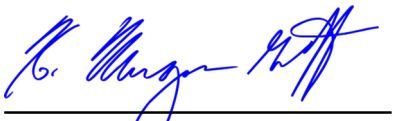

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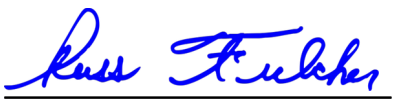

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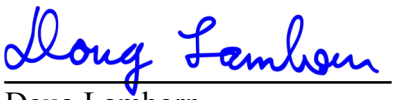
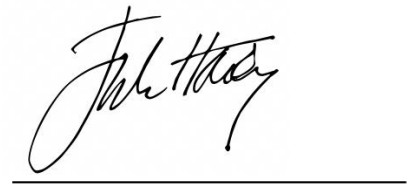
Eric A. "Rick" Crawford
Member of Congress



Doug Lamborn
Member of Congress

John Hoeven
United States Senator



Josh Hawley
United States Senator

CC:
The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services